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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | | |
|---|-----------------|----------------------|---------------------|------------------|--|--|--|
| 09/836,462 | 04/18/2001 | Alexander Walland | 1/1152/1088 | 7878 | | | |
| 28501 | 7590 02/26/2003 | | | | | | |
| BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877 | | | EXAMI | EXAMINER | | | |
| | | | MORRIS, PATRICIA L | | | | |
| | | | ART UNIT | PAPER NUMBER | | | |
| | | | 1625 | | | | |

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No | . An | plicant(s) | | | |
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| Office Action Summary | Examiner | Wi | | Group Art Unit | | |
| -The MAILING DATE f this communication ap | pears on the cover | sheet bene | ath the cor | respondence a | ddress | |
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SI OF THIS COMMUNICATION. | ET TO EXPIRE 4h | n N | MONTH(S) I | FROM THE MAII | LING DATE | |
| Extensions of time may be available under the provisions of 37 C from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days If NO period for reply is specified above, such period shall, by defended to reply within the set or extended period for reply will, by | s, a reply within the statu fault, expire SIX (6) MO | ory minimum o | f thirty (30) da mailing date (| ays will be considered | ed timely. | |
| Status | · | | | | | |
| Responsive to communication(s) filed on $11-25$ | -07 | | | | | |
| This action is FINAL . Since this application is in condition for allowance exaccordance with the practice under <i>Ex parte Quayle</i> , | cept for formal matte 1935 C.D. 1 1; 453 | rs, prosecut D.G. 213. | ion as to ti | ne merits is clos | sed in | |
| Disposition of Claims | | | | • | * | |
| (Claim(s) 1-17 | | is/are pending in the application. | | | | |
| Of the above claim(s) 6,8,11,12 and 14 | | is/are withdrawn from consideration. | | | | |
| □ Claim(s) | | is/are allowed. | | | | |
| □ Claim(s) 1-5,7,9,10,13 ord 17 | | is/are rej | • | | | |
| Claim(s) | | | is/are ob | | | |
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| Applicati n Papers | | | requirem | | 01 010011011 | |
| ☐ See the attached Notice of Draftsperson's Patent Dra | awing Review PTO-9 | 48 | • | | | |
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U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No.

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DETAILED ACTION

Claims 1-5, 7, 9, 10, 13 and 17 are under consideration in this application.

Claims 6, 8, 11, 12 and 14-16 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b). Claims 11 and 16 are held withdrawn from consideration since they are improper hybrid claims in that they combine a process of preparing with a compound claim. Applicants **elected** compounds and not processes of preparing.

Election/Restriction

The restriction requirement is deemed sound and proper and is hereby made FINAL.

This application contains claims 6, 8 and 11-16 and compounds drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Again, this application has been examined with respect to the elected compound wherein R^1 represents and R^2 , R^5 and R^6 as set forth in claim 1, exclusively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 9, 10, 13 and 17 are rejected under 35 U.S.C. 103(a) as being obvious over the combined teachings of Schromm et al. I, II (US 5,223,614) for the reasons set forth in Paper no. 7.

Again, Schromm et al. I, II generically embrace the instant compounds wherein R⁵ represents methoxy and dimethylamino. Note, for example, the compounds recited in claim 1 of Schromm et al. I

Further, example 30 of Schromm et al. differs from the compound claimed herein as having a hydroxy group rather then applicants' methoxy group. The motivation to make these compounds is their close structural similarities to the disclosed compound. Note that the disclosed compound has pharmaceutical activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties.

A compound need not be a homolog or isomer of a prior art compound in order to be susceptible to a rejection based on structural obviousness. The name used to designate the structural relationship between compounds is not controlling, it is the closeness of that relationship. Note: <u>In re</u> Payne et al., 203 USPQ 245. When chemical compounds have a "very close" structural similarity and similar utilities, a prima facie case of obviousness may be made, note <u>In re</u> Grabiak, 226 USPQ 870, "without more". Thus, a difluorinated compound was held

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unpatentable over the prior art dichloro compound on the basis of similar reasoning to the above; Ex parte Wiseman (POBA 1953) 98 USPQ 277.

Applicants merely contend that the rejection is improper. The motivation to produce the instant compounds is not abstract but is always related to the <u>properties or uses</u> that one having ordinary skill in the art would have expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, one would not have to modify the disclosure of the references, but merely employ compounds that are generically embraced by the disclosed formulas of the references. As previously discussed, the requisite motivation for producing the claimed compounds stems from the fact that they are generically disclosed. Therefore, one having ordinary skill in the art would have found it *prima facie* obvious to select any on the compounds embraced by the generic formula, including those of the claims, with the expectation that each of them can be used as a pharmaceutical agent.

Applicants do not point to any objective evidence which demonstrates that the claimed compounds as a class exhibit any properties which are actually different from the closest prior compounds embraced by Muller et al. <u>In re Wilder</u>, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); <u>In re Hoch</u>, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970).

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term preparation in claims 13 and 17 is unclear to its meaning? Are applicants claiming a composition or a process? If applicants intend a composition, it is suggested preparation be changed to composition to clearly claim they as such

Conclusion

Applicant's arguments filed November 25, 2002 have been fully considered but they are not persuasive.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final

action.

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

February 21, 2003